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A61M 1/00

(52) UK CL (Edition Q)
A5R RCEB RCEX

(56) Documents Cited
WO 96/05873 A WO 94/20041 A WO 93/09727 A
US 5260066 A US 4342745 A

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ONLINE: EPODOC, WPI, JAPIO

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(54) Abstract Title
APPARATUS FOR APPLYING NEGATIVE PRESSURE TO A WOUND

(57) Apparatus for stimulating the healing of superficial wounds by applying negative pressure comprises a porous pad of open, intercommunicating cellular, flexible foam formed from polyvinyl alcohol, a suction tube for connecting the pad to a pump and a surgical drape for forming an air-tight seal over the wound and over the pad. A connector comprising a disc-like cup (601) having a spout (602) connects the pad with the suction tube and preferably projects through hole (702) in the drape. In use (Fig 4;not shown), wound exudate is drawn from the pad into a canister (100) via a catheter using portable suction pump (6) which is worn on a harness or belt. Overfilling of canister (100) is prevented by a filter contained in the canister and a pressure sensor which detects pressure reductions in tube (103) between the canister and pump which occur when exudate covers the filter. Contamination of pump (6) is prevented by a further filter placed between the pump and canister (100) and pressure at the wound site is monitored by a conduit connected to the porous pad.

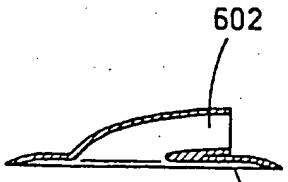


Fig. 6B

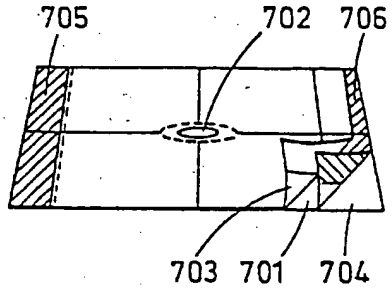


Fig. 7B

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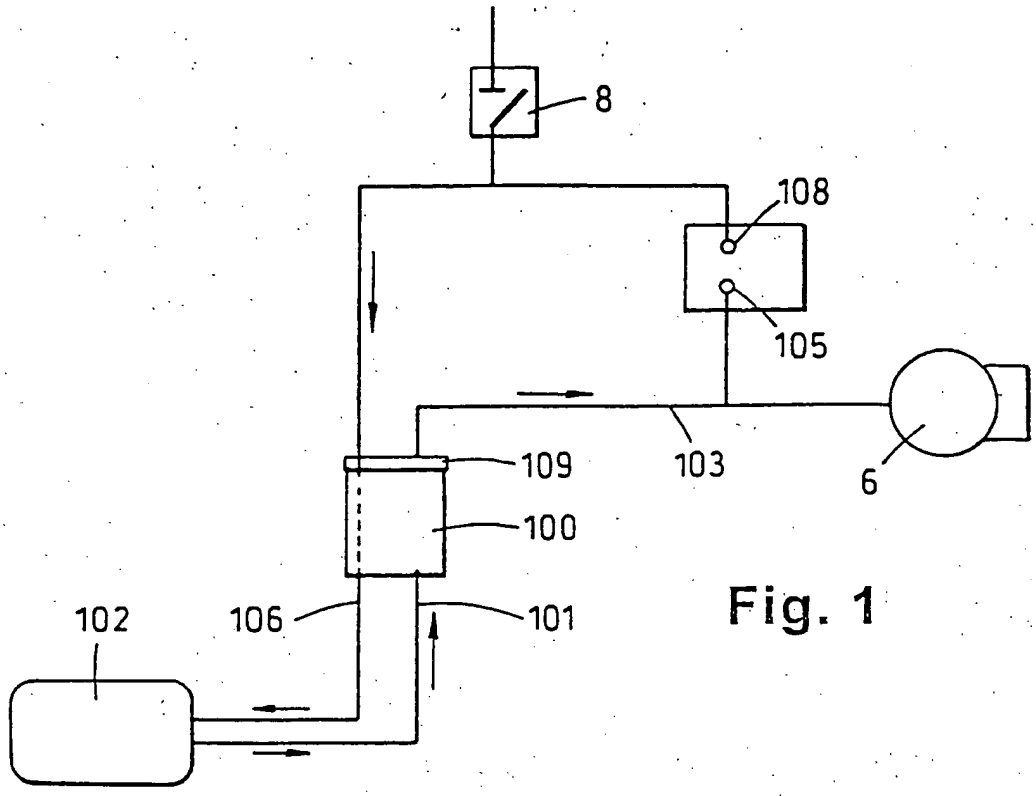


Fig. 1

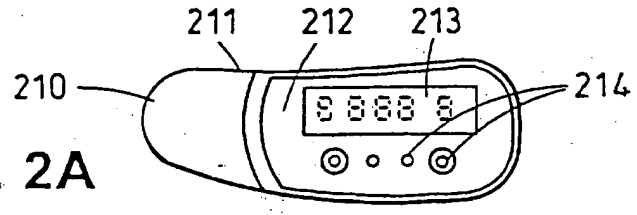


Fig. 2A

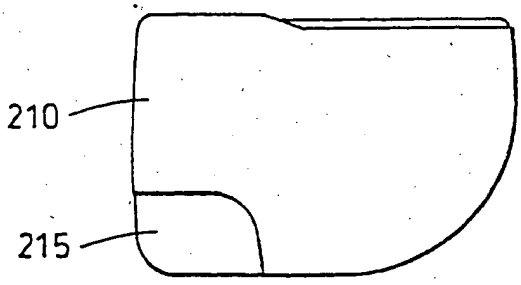


Fig. 2B

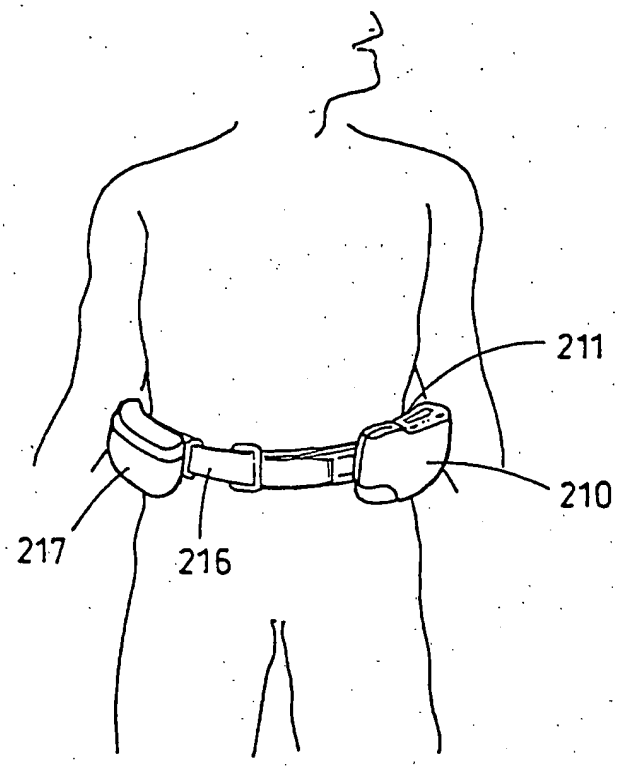


Fig. 3A

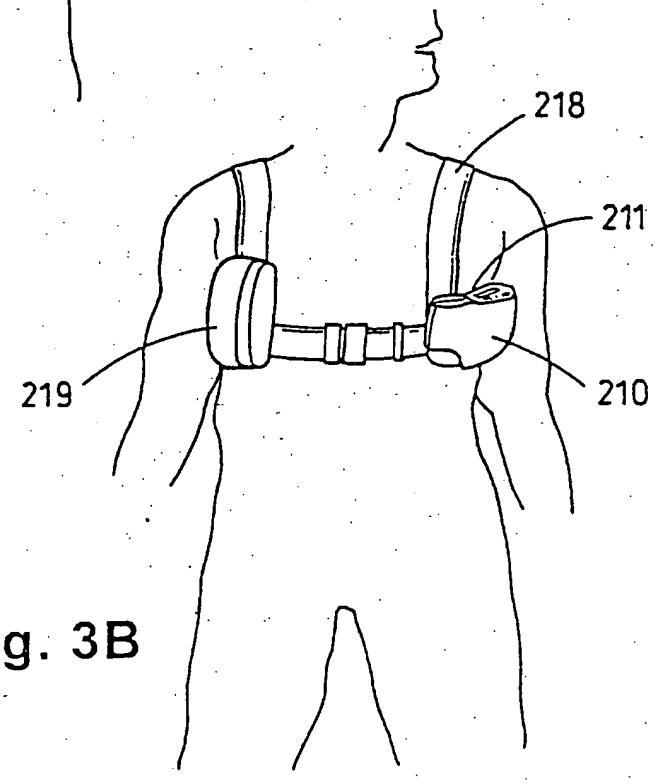


Fig. 3B

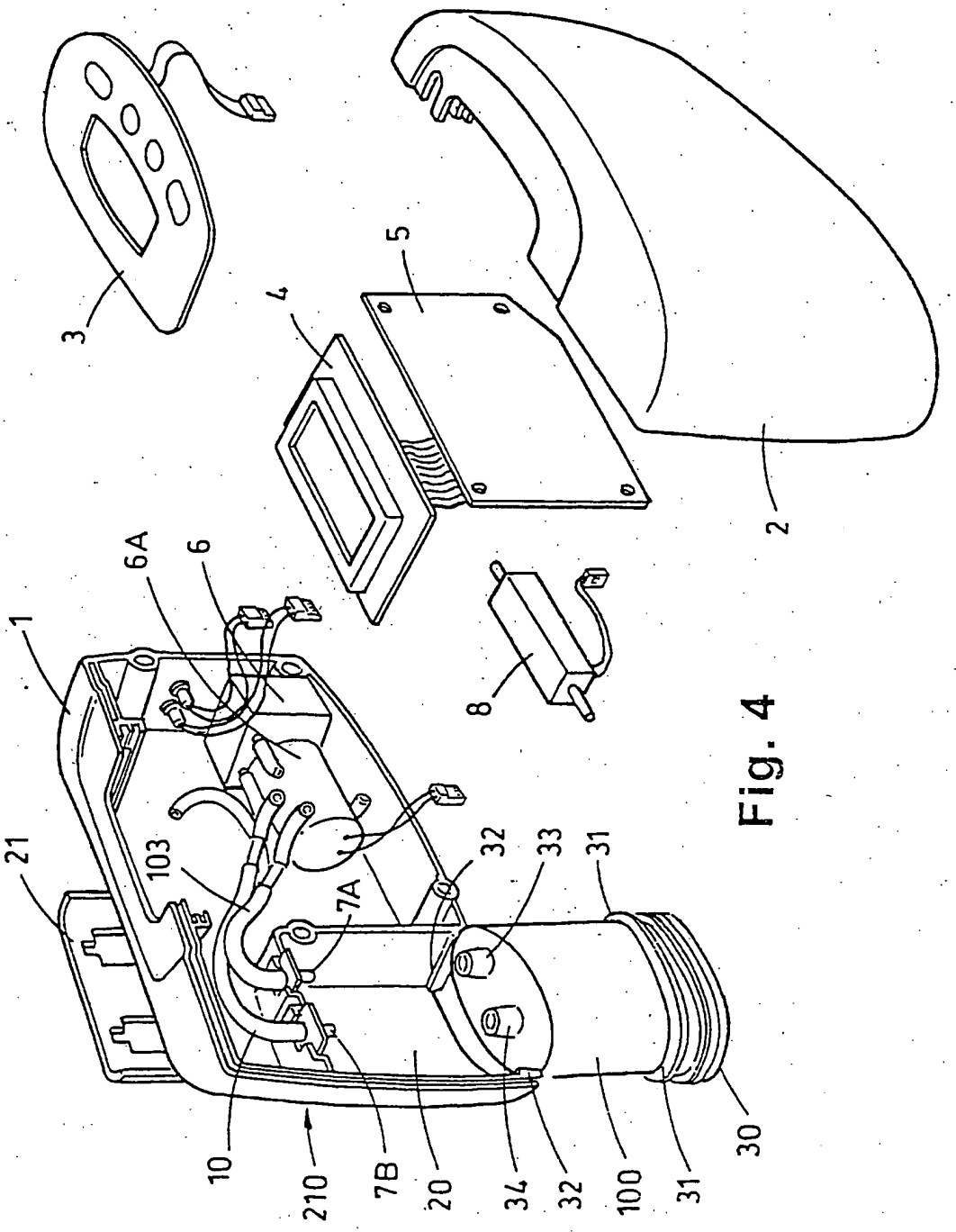


Fig. 4

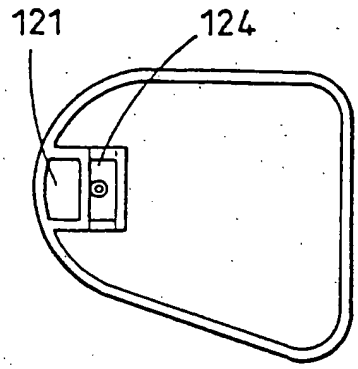


Fig. 5A

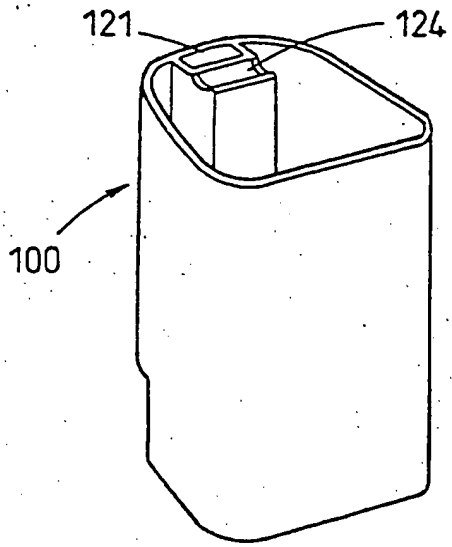


Fig. 5D

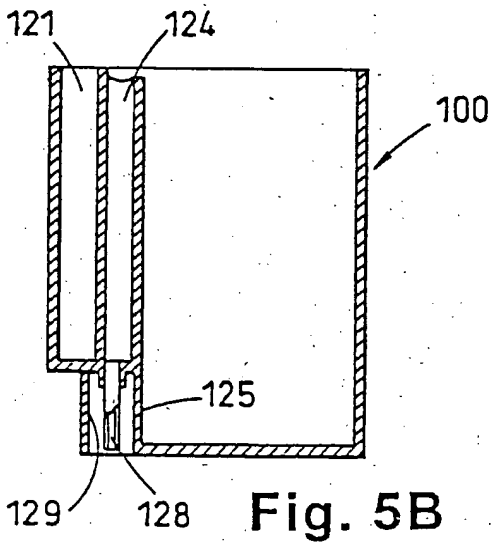


Fig. 5B

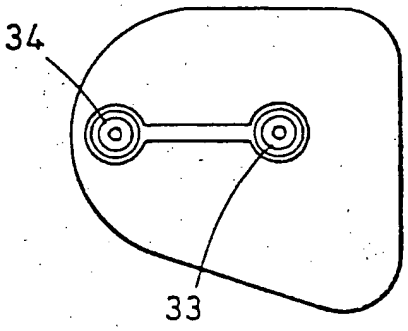


Fig. 5E

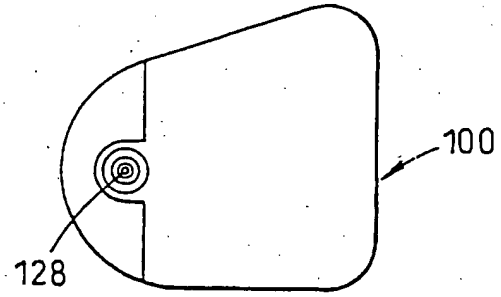


Fig. 5C

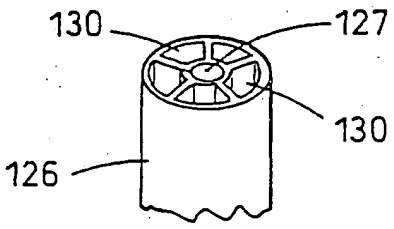


Fig. 5F

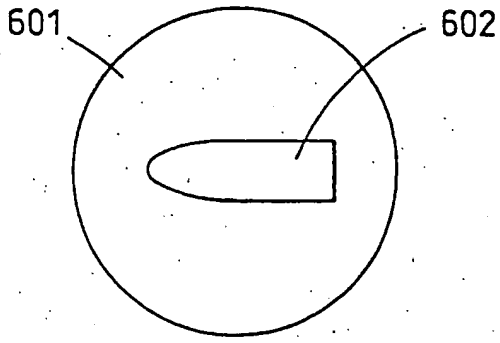


Fig. 6A

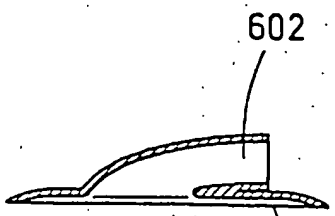


Fig. 6B

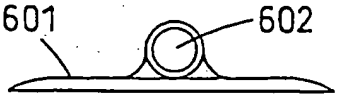


Fig. 6C

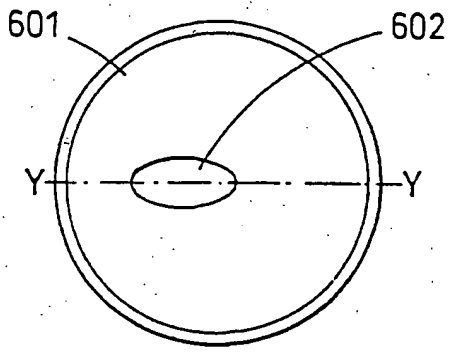


Fig. 6D

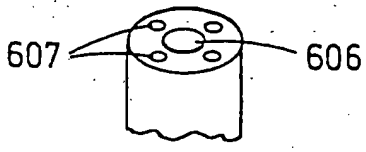


Fig. 6E

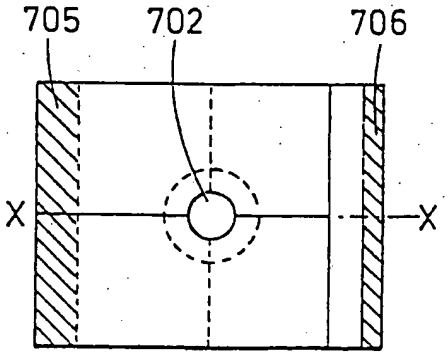


Fig. 7A

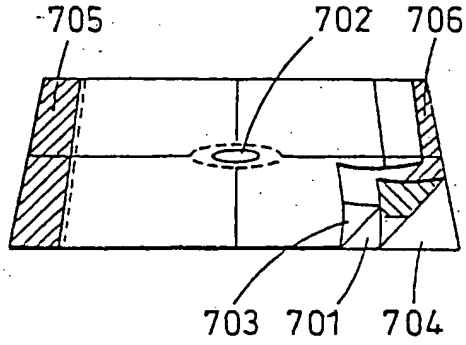


Fig. 7B

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# PORTABLE WOUND TREATMENT APPARATUS

This invention relates to the healing of wounds and, more particularly, to apparatus for stimulating the healing of superficial wounds.

PCT Application No. GB95/01983 (WO 96/05873) describes apparatus for stimulating the healing of wounds comprising a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, and a canister for collecting fluids sucked from the wound. The apparatus described in the above application has proved to be clinically effective but there are some limitations in its use.

The apparatus described in the above PCT application is effective for treating a wide variety of different types and sizes of wounds. However, it may require the patient to undergo treatment on the apparatus for a long period. In cases where the patient is confined to bed this may not be a major problem, but where the patient is mobile it means that he or she would be confined for long periods while the treatment takes place.

An object of this invention is therefore to provide apparatus which can be used more conveniently, especially by patients who are reasonably mobile, and which has certain further advantages which will become apparent from the following description.

According to one aspect of the present invention there is provided a portable therapeutic apparatus for stimulating the healing of superficial wounds in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including

means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

Typically, the housing will have a curved surface on the side intended to be supported against the person's body so as to make the apparatus more comfortable to wear. In addition, controls and indicators indicating the status of the treatment being applied to the wound are preferably located on the upper side of the housing so that the patient can easily see, e.g. the level of suction pressure being applied and the programme for such treatment.

The suction pump is conveniently driven by an electric motor and batteries for such motor may be contained within the housing. However, it is generally more convenient to provide a separate housing for the batteries since these can be placed on the belt or harness in such a way as to balance the weight of the housing, preferably in a housing shaped similarly to the housing for the pump and canister. The canister should be removably mounted within the housing, e.g. by means of a latch or similar release mechanism, so that the canister can be readily removed and replaced when full.

In a portable therapeutic apparatus (in contrast with a static apparatus of the kind described in the above PCT application which cannot be easily carried by the patient), it is less easy to determine the pressure prevailing at the wound site being treated. This is because the pressure will depend, in part, upon the hydrostatic height between the pump and the wound being treated and this height may vary during the treatment, depending upon the patient's movements. Apparatus in accordance with the invention overcomes this problem by providing an additional conduit connecting the wound site or an area close thereto to a pressure-detecting means, preferably located in the housing. The pressure-detecting means can be linked to a microprocessor programmed to maintain such pressure within a

predetermined range irrespective of the movement of the patient. This can be done by, for example, signalling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced. This feature can also be used in a static therapeutic apparatus of the kind described in the above-mentioned PCT application.

In the apparatus described in the above PCT application, the level of liquid in the canister is monitored by capacitance measurement. It has now been found that a simpler way of determining when the canister is filled is by measuring or detecting the pressure drop across the canister. The pressure drop can be increased by providing a filter barrier in the region of the outlet end of the canister. Thus, when the liquid reaches a level within the canister so as to substantially occlude the filter, a sharp pressure change occurs in the conduit between the canister and the pump. By monitoring this pressure change, the point at which the canister is filled can be accurately determined.

Additional advantages and features of the present application will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is a schematic layout of the apparatus in accordance with the invention,

Figure 2A and B are pictorial representations of the housing of the pump and canister,

Figure 3A and B are pictorial representations of the apparatus supported on a belt and harness respectively,

Figure 4 is an exploded view of the housing showing the contents,

Figures 5A to F show various views of a preferred form of the canister and a section of a multi-lumen tube, and

Figures 6A to D show various views of a foam dressing connector for connecting the housing to the dressing,

Figure 6E shows a section of a modified multi-lumen tube,

Figures 7A & 7B show a plan and perspective view of a surgical drape for use with the apparatus.

Referring to the drawings, the portable therapeutic apparatus comprises a housing 210 (best shown in Figures 2A and 2B), having rounded corners and a side 211 which is concavely curved in order to fit comfortably to the wearer's body. The shaping of the housing with curved surfaces is to avoid sharp corners or edges which could dig in to the user or his carer. The upper surface 212 is generally flat and has an LCD screen 213 on which details such as applied pressure can be displayed. Control buttons 214 are provided to adjust pressures and treatment intervals. Provision is made for housing a canister within the housing and a snap release cover 215 is arranged for removing or introducing the canister.

Figures 3A and 3B show schematically ways in which the housing 210 may be supported on the patient's body. In Figure 3A the housing 210 is supported on a belt 216 and its weight is balanced by a similarly rounded casing 217 containing a rechargeable battery pack. Figure 3B shows an alternative arrangement in which the housing is supported on a harness 218 and again a battery pack is contained in a housing 219, also supported on the harness.

Figure 4 shows an exploded view of the housing 210 indicating the main components within the housing. The housing consists of front and rear shell mouldings 1 and 2 having an external belt clip 21 for attachment to a belt or harness.

Within housing shell 1 is located a suction pump 6 with associated electric motor 6A and the pump is connected by a silicon rubber tube 103 to a canister

spigot 7A in a compartment 20 for the canister 100. Also connected to a second canister spigot 7B via a tube 10 is a pressure relief valve 8 and both tubes 103 and 10 are connected via T-connectors T to pressure transducers (not shown). A microprocessor 4 is mounted on a PCB board 5 and a membrane assembly 3 incorporates an LCD indicator and control buttons.

The apparatus may include means for recording pressures and treatment conditions given to a particular patient which may be printed out subsequently by the physician. Alternatively, the equipment may include a modem and a telephone jack so that the conditions under which the patient has been treated can be interrogated by the physician from a distant station.

Canister 100 is a push fit into the cavity 20 and its lower end is supported in a cover 30. The cover 30 incorporates fingers 31 which are releasably engageable with lips 32 to hold the canister in position. The canister and the latch mechanism is arranged so that when the latch is engaged, the spigots 7A and 7B are in sealing engagement or abutment with tubular protrusions 33 and 34 formed in the top of the canister.

The method of operation of the apparatus can be appreciated from the schematic layout in Figure 1, in which the canister 100 is connected via tube 101 to a porous dressing 102 at the wound site. Suction is applied to the wound site via the canister by a tube 103, connected to the pump 6. The pressure in the tube 103 is detected by the transducer 105.

A second tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8 and to a second transducer 108. Tubes 106 and 101 can be combined in a multi-partitioned tube in manner to be described later. By means of tube 106 and transducer 108 the pressure at the wound site can be measured or monitored. A filter 109 is placed at or close to the outlet end of the

canister 100 to prevent liquid or solid particles from entering the tube 103. The filter is a bacterial filter which is hydrophobic and preferably also lypophobic. Thus, aqueous and oily liquids will bead on the surface of the filter. During normal use there is sufficient air flow through the filter such that the pressure drop across the filter is not substantial.

As soon as the liquid in the canister reaches a level where the filter is occluded, a much increased negative pressure occurs in tube 103 and this is detected by transducer 105. Transducer 105 is connected to circuitry which interprets such a pressure change as a filled canister and signals this by means of a message on the LCD and/or buzzer that the canister requires replacement. It may also automatically shut off the working of the pump.

In the event that it is desired to apply intermittent suction to the wound site, a pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if the apparatus is programmed, for example, to relieve pressure at 10 minute intervals, at these intervals valve 8 will open for a specified period, allow the pressure to equalise at the wound site and then close to restore the suction. It will be appreciated that when constant suction (or negative pressure) is being applied to the wound site, valve 8 remains closed and there is no leakage from atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running the pump continuously, but only from time to time, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric), which is detected by the transducer 105. This saves power and enables the appliance to operate for long periods on its battery power supply.

Instead of running two separate tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by

an annular space represented by tube 106. This is illustrated in Figures 5A to 5F and in a modified form in Figure 6E.

In an alternative embodiment, the multi-lumen tube may be constructed as shown in Figure 6E. In this embodiment, the internal bore 606 comprises the line 101 (see Figure 1) and is used to extract fluids from the wound site. Air flow (represented by line 106 in Figure 1) passes down conduits 607 located within the walls of the tube. By spacing the conduits 607 at 90° intervals around the tube, the risk of arresting the air flow by kinking or twisting the multi-lumen tube is minimised.

Figure 5E is a plan view of the top of a preferred shape of canister, the generally triangular shape in section being chosen to fit better the space within cavity 20 (see Figure 4). Tubular protrusions on the top of the canister are connected internally of the canister with respectively conduits 124 and 121 (see sectional view of Figure 5B), thus maintaining a separation between the tubes which are represented by lines 103 and 106 in Figure 1. At the base of the canister, a moulding 125 facilitates connection to a multi-partitioned tube 126 shown in Figure 5F. Tube 126 has a central bore 127 which is sized to fit over a spigot 128 in moulding 125. At the same time, the external wall of tube 126 seals against the inner wall 129 of moulding 125. Thus, compartment 124 will connect with central bore 127 and the compartment 121 will connect with the annular spaces 130 of tube 126. In this way, a conduit 130 corresponds with line 106 and central bore 127 with line 101 as shown in Figure 1.

The partitioned tube need not continue all the way to the wound site 102, but can be connected to a short section of single bore tube close to the wound site.

In the event of an air leak in the dressing at the wound site 102, this can be detected by both transducers 105 and 108 reading insufficient negative pressure for

a specific time period, and then triggering a leak alarm, i.e. a message on the LCD, preferably also with an audible warning.

Typically, the pump 6 is a diaphragm pump but other types of pumps and equivalent components to those specifically employed may be substituted.

Figures 6A~6D show various views of a connector for attaching the multi-lumen tube at the wound site. Figures 7A and 7B show a plan and perspective view of a surgical drape for attaching the connector to a porous dressing at the wound site. The connector comprises a moulded plastics disc-like cup 601 having a centrally positioned spout 602. The spout 602 is sized to accept, as a closely sliding fit, the end of a multi-lumen tube e.g. of the kind shown in Figures 5F or 6E. In use, a porous dressing is cut to correspond with the extent of the wound and pressed onto the wound as shown in Figure 10 of our above cited PCT application WO 96/05873. Instead of introducing the lumen into the foam dressing, the cup 601 is pressed onto the porous dressing and secured by a surgical drape. However, if desired, the end of the lumen can be passed into the spout and additionally pressed into the foam. A surgical drape such as shown in Figures 7A and 7B, can be used to secure the connector, lumen and dressing. The drape comprises a polyurethane film 701 coated on one side with a pressure-sensitive acrylic resin adhesive. A hole 702 is cut through all layers of the drape and the hole is dimensioned to correspond approximately with the outer cross-section of the spout 602. Film 701 has an overall size which allows it to be adhered to the patient's skin around the wound site, while at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so that an air-tight cavity is formed around the wound.

In an alternative form, the drape can be made in two parts, e.g. by cutting along the line X-X in Figure 7A. With this arrangement, the wound can be sealed

by overlapping two pieces of surgical drape so that they overlap each other along a line Y-Y as shown in Figure 6D.

The surgical drape may include a protective film 703, e.g. of polyethylene, and a liner 704 which is stripped off prior to use to expose the pressure-sensitive adhesive layer. The polyurethane film may also include handling bars 705,706, which are not coated with adhesive; to facilitate stretching of the film over the wound site. The dressing is preferably a pad of porous, flexible plastics foam, e.g. reticulated, open intercommunicating cellular flexible polyurethane foam, especially of the kind described in the above-mentioned PCT application WO 96/05873.

Alternatively, a reticulated intercommunicating cellular foam made from flexible polyvinylacetate or polyvinylalcohol foam may be used. The latter is advantageous because it is hydrophilic. Other hydrophilic open celled foams may be used.

In another method of therapy, the foam dressing may be sutured into a wound after surgery and the foam dressing connected to the pump unit by the multi-lumen catheter. Negative pressure can then be applied continuously or intermittently for a period determined by the surgeon, e.g. from about 6 hours to 4 to 5 days. After this period, the dressing is removed and the wound re-sutured. This therapy improves the rate of granulation and healing of wounds after surgery.

CLAIMS:-

1. Apparatus for applying negative pressure to a superficial wound in a mammal which comprises a porous pad of open, intercommunicating cellular, flexible foam formed from polyvinyl alcohol, a suction tube for connecting the pad to a pump and a surgical drape for forming an air-tight seal over the wound and over the pad.

2. Apparatus for applying negative pressure to a superficial wound in a mammal which comprises a porous pad of open, intercommunicating cellular flexible foam, a suction tube for connecting the porous pad to a pump, a surgical drape for forming an air-tight seal over the wound and over the pad and a connector for connecting the pad to the suction tube, said connector comprising a disc-like cup having a spout for connection to the suction tube.

3. Apparatus according to claim 2 wherein the porous pad comprises a polyvinyl alcohol foam.

4. Apparatus according to claim 2 or 3 wherein the surgical drape has a hole for the spout to project therethrough.

5. Apparatus according to claim 4 wherein the surgical drape comprises a plastics film which is coated with a pressure-sensitive adhesive for securing the porous pad and connector to the wound.

6 A portable therapeutic apparatus for stimulating the healing of a superficial wound in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

7 Apparatus as claimed in claim 6 wherein the housing has a curved surface on the side intended to be supported against the person's body, and controls located on an upper side of the housing.

8. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and a filter barrier located in the canister at the outlet side, and pressure detecting means arranged to detect pressure changes in the tube between the canister and the pump and to signal a pressure change when liquid in the canister covers a substantial part of the filter barrier, thus indicating a full canister.

9. Apparatus as claimed in claim 8 wherein the filter barrier covers the entire outlet from the canister and the dimensions of the pores in said barrier are such that when liquid covers substantially the whole of the filter barrier, said pressure detecting means signals a sharp increase in negative pressure in the tube connecting the canister with the pump.

The Patent Office

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INVESTOR IN PEOPLE

| | | | |
|---|---|---|---|
| **Application No:** | GB 9919710.5 | **Examiner:** | Susan Chalmers (Mrs) |
| **Claims searched:** | 1-5 | **Date of search:** | 17 September 1999 |

## Patents Act 1977
## Search Report under Section 17

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.Q): A5R: RCEA, RCEB, RCEC, RCED, RCEX, RCX, RED

Int Cl (Ed.6): A61B: 19/00, 19/08; A61L 15/00, 15/24, 15/42; A61M: 1/00

Other: ONLINE: EPODOC, WPI, JAPIO

**Documents considered to be relevant:**

| Category | Identity of document and relevant passage | | Relevant to claims |
|---|---|---|---|
| Y | WO 96/05873 A1 | (KINETIC CONCEPTS INC) see Figures 5 and 10 and page 7 line 19 to page 9 line 10 | 1 |
| X,Y | WO 94/20041 A1 | (WAKE FOREST UNIVERSITY) see Figures 1, 5 and 10, page 10 line 22 to page 11 line 20, page 12 line 8 to page 17 line 8 and page 23 line 31 to page 24 line 33 | 1,3 (IS) 2,4,5 (N) |
| Y | WO 93/09727 A1 | (WAKE FOREST UNIVERSITY) see Figure 1, Example 4 and page 7 line 28 to page 8 line 32 | 1 |
| Y | US 5260066 | (SRCHEM INC) see eg Examples | 1,3 |
| Y | US 4342745 | (ZYMA SA) whole document | 1,3 |

| | | | |
|---|---|---|---|
| X | Document indicating lack of novelty or inventive step | A | Document indicating technological background and/or state of the art. |
| Y | Document indicating lack of inventive step if combined with one or more other documents of same category. | P | Document published on or after the declared priority date but before the filing date of this invention. |
| & | Member of the same patent family | E | Patent document published on or after, but with priority date earlier than, the filing date of this application. |

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GB 0692578 A US 5437622 A

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UK CL (Edition Q) A5R RED
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(54) Abstract Title
SURGICAL DRAPE

(57) The invention relates to a surgical drape comprising a thin, flexible, adhesive-coated plastics film (21) and a strengthening layer (20) applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer (24) applied to the adhesive coating, the drape having an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar (23) for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap (27) overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

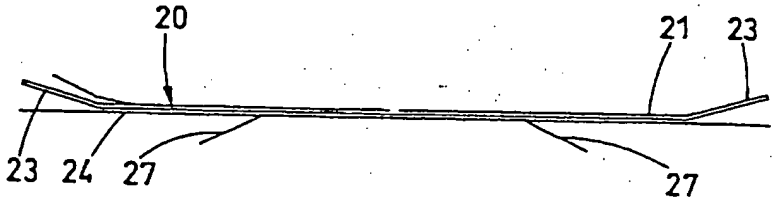


Fig. 3

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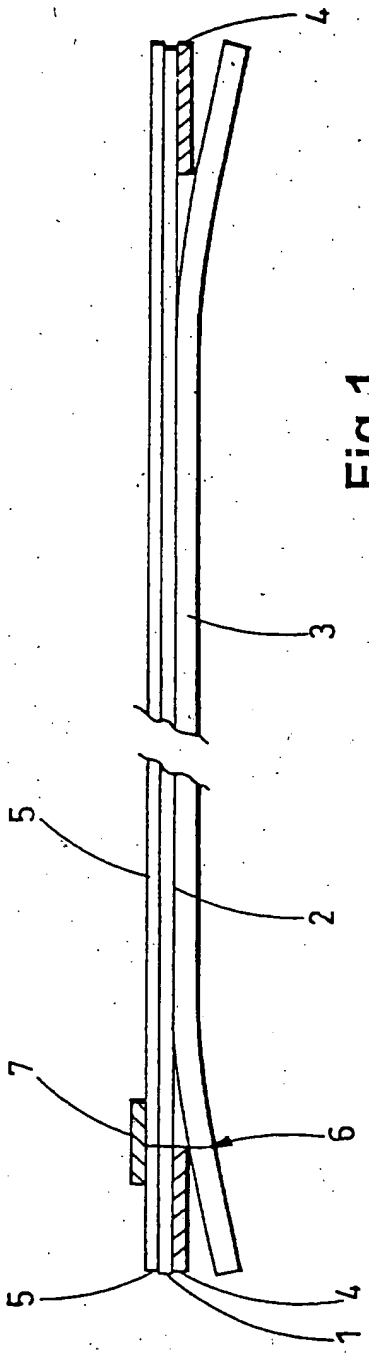


Fig.1

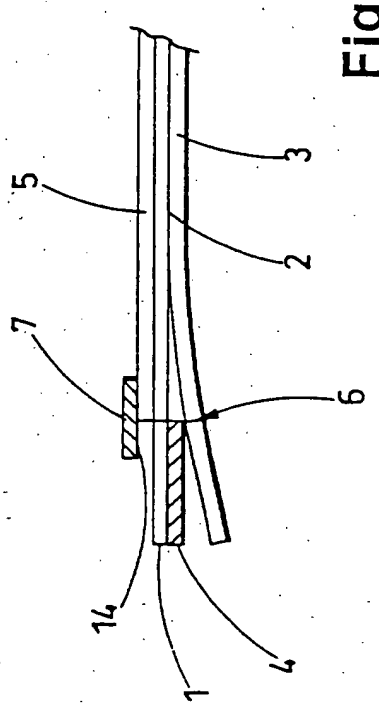


Fig. 2

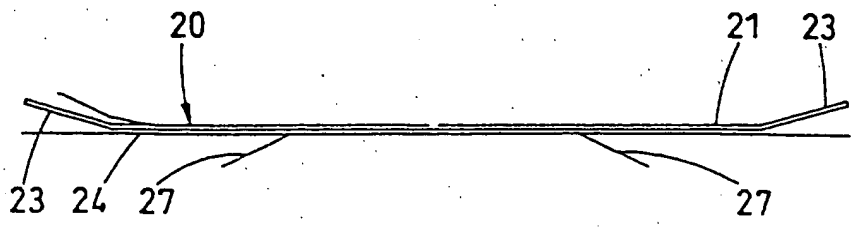


Fig. 3

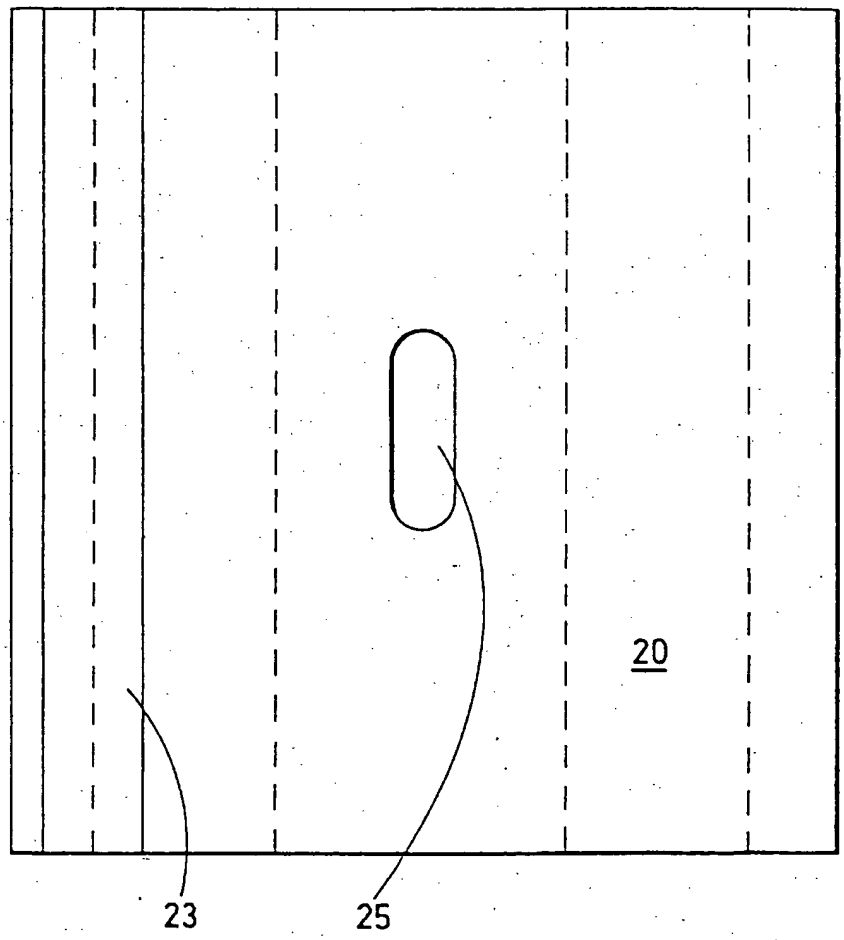


Fig. 4

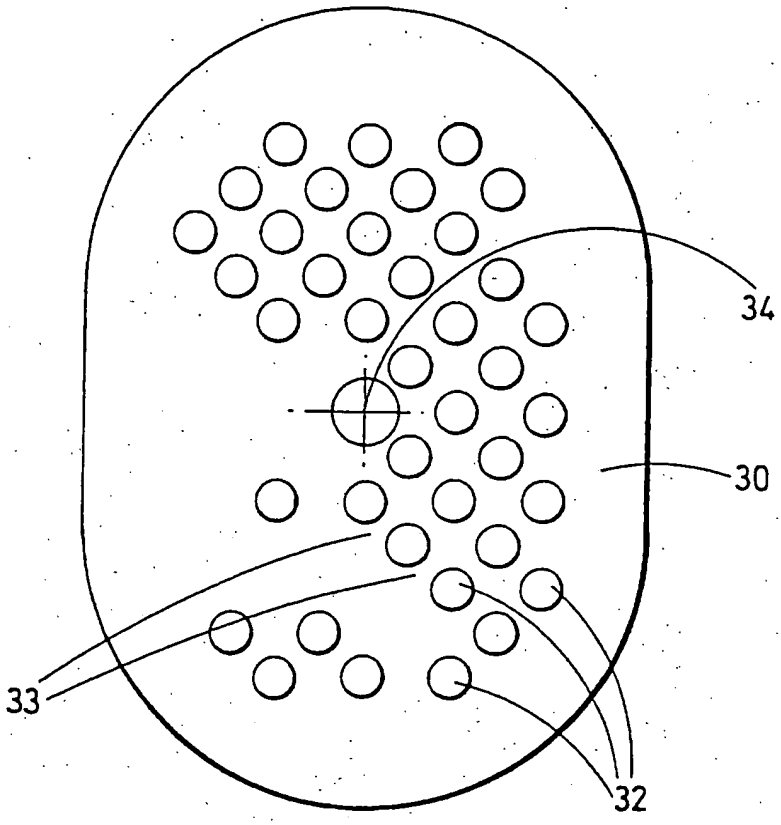


Fig. 5

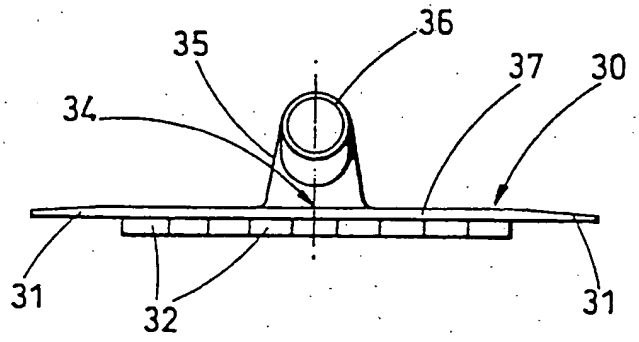


Fig. 6

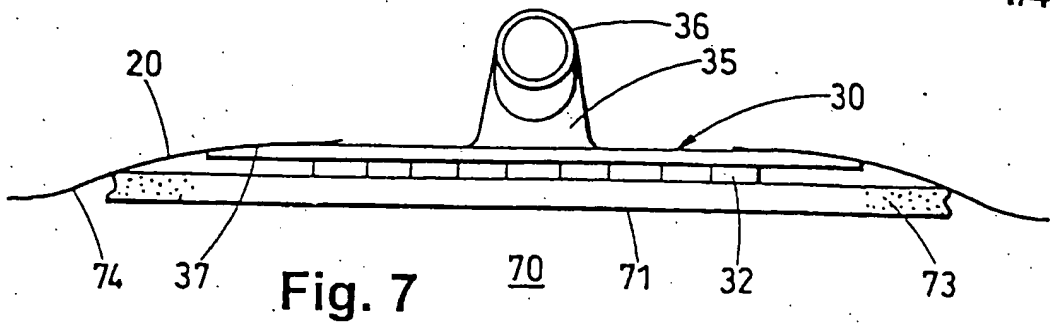


Fig. 7

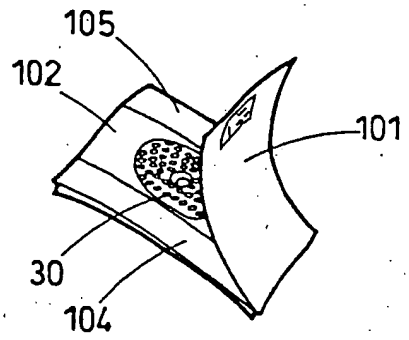


Fig. 8

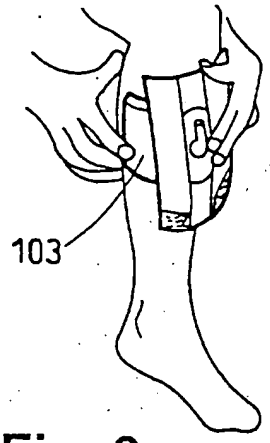


Fig. 9a

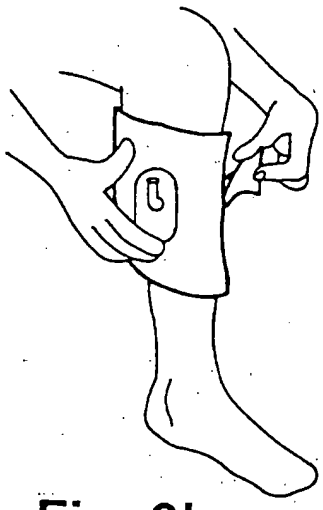

Fig. 9b

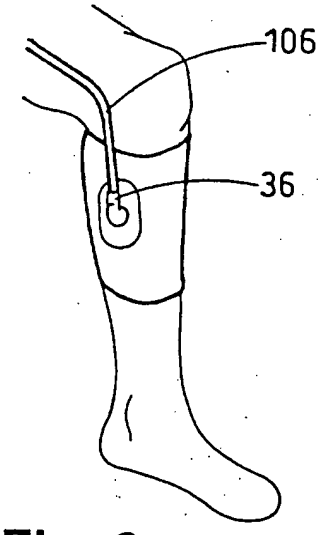


Fig. 9c

## Surgical Drape and Suction Head for Wound Treatment

This invention relates to surgical drapes and suction heads for wound treatment.

Surgical drapes are widely used in surgical operations for the purpose of reducing infection and facilitating the handling of skin around incisions. Normally, they are transparent or translucent. Typically, they consist of a flexible, plastics film which is adhesive-coated and which is applied to the area of the operation, prior to making the incision. Surgical drapes are also used for attaching treatment devices to patients after an operation, such as catheters or drainage tubes.

A further, recently developed use is for connecting a suction tube to a wound for the purpose of stimulating healing of the wound. Such use is described in our earlier PCT Applications Nos. WO 96/05873 and WO 97/18007.

Various proposals have been made in the past to design the surgical drape so that handling of the sticky, flexible, plastics film is facilitated. For example, US Patent No. 5,437,622, describes a surgical drape which is a laminate of three materials. The first material comprising a transparent, thin plastics film which is adhesive-coated and this is protected with a layer of release-coated paper. The other face of the adhesive-coated film is strengthened with a reinforcing layer of a less flexible, plastics film. Handling bars or strips are attached to the flexible, plastics film at its lateral edges to facilitate handling of the flexible, plastics film after stripping away the protective releasable layer.

Where it is desired to use a surgical drape primarily to attach a device such as a catheter to a wound area after an operation or for long term treatment, it is inconvenient for the surgeon or nurse to have to adapt a standard surgical drape for this purpose. It would be more convenient to have a surgical drape which was suitable without adaptation to accommodate the treatment device.

One aspect of the present invention is directed to a solution to this problem. A second aspect provides a combined surgical drape and suction head for applying suction to a wound area to facilitate application of negative pressure therapy.

According to one aspect of the present invention there is provided a surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the strengthening and adhesive-coated film to permit, in use, access to a wound area, a first edge of the drape having non-adhesive coated handling bars for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries a flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use. Preferably, non-adhesive-coated handling bars are positioned at opposite lateral edges of the drape.

In practice, surgical drapes may be manufactured by laminating an adhesive-coated flexible film, such as a polyurethane film, to a protective releasable layer, such as a siliconised paper. A strengthening layer of thicker plastics material, e.g. a polyolefin such as polyethylene, may be applied to the non-adhesive coated face of the flexible film, so that a three-layer laminate is produced. These laminates are produced in substantial width and may be slit longitudinally to the desired width and then laterally to form drapes of the desired size.

After slitting to a desired width, handling bars are normally applied to the adhesive-coated layers at one or both lateral edges to facilitate separation of the film from the protective, releasable layer. While an aperture could be cut at the desired position through the layers to accommodate a catheter or a device such as those described in our above-mentioned applications, it is difficult to handle the highly pliable and adhesive film after the releasable layer has been stripped off.

Although the strengthening layer does somewhat improve the handling characteristics, this is not a complete answer to the problem. However, the handling

characteristics are substantially improved by providing a protective layer which is in at least two portions, one of which is in the form of a strip, e.g. one extending parallel to the lateral edges of the drape, and covering the peripheral area around the aperture through the drape. By providing a flap on this portion of the releasable layer, it can be stripped off initially so that the drape is first positioned around the device which is to pass through the aperture, and then the remaining part of the protective releasable layer is stripped off to adhere the drape to the patient's skin around the area to be treated.

In a preferred form of the invention in which negative pressure therapy is applied to a wound area, the surgical drape described above is combined with a suction head having a connector piece which is adapted to be connected to a suction tube. Thus, in this embodiment, the suction head can be adhered to the patient's skin in the area of the wound after removing the strip of protective releasable layer, and then the remaining part of the drape affixed to the patient's skin. In this way, the suction head is held firmly in place and, at the same time, seals the suction head to the wound area and prevents leakage of air from atmosphere into the wound area.

The invention also includes a suction head having a design which facilitates the suction of fluid from a wound area.

According to a further feature of the invention, therefore, there is provided a suction head for applying suction to a wound area which comprises a generally planar flange portion and a tubular connector piece on a first face, for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels facilitating flow of fluid towards said aperture.

Preferably, the suction head described above is combined with a surgical drape, the drape comprising a thin, flexible, adhesive-coated plastics film, and the tubular connector piece extends through an opening in the plastics film with the adhesive coating adhered to said first face of the flange portion.

Preferably, the suction head is used in conjunction with an open-celled foam pad so that one surface of the foam pad is placed in contact with a wound area and the

suction head applied to the other surface of the foam pad. In the case of deep wounds the foam may be shaped and placed so that it is packed into the wound cavity as described in our above cited PCT applications. According to another technique, which is particularly applicable to superficial wounds, the foam pad may be a relatively thin pad which is placed over the wound. The suction head is placed in contact with the open face of the foam pad and the drape applied over the suction head to fix the assembly to the patent's skin.

Various types of open celled foams can be used as described in our above cited PCT applications. The foam may be a polyurethane foam but polyvinyl acetate (pva) foams are preferred, especially when used as a pad which is placed over the wound. These are to some extent hydrophilic, which seems to exhibit beneficial comfort properties when applied to the skin. Wound healing is stimulated by maintenance of moist conditions in the wound area, and this is facilitated by using a hydrophilic foam.

Further features and advantages of the present invention will be apparent from the following description and accompanying drawings, of non-limiting examples in accordance with the invention.

Referring to the accompanying drawings:-

Figure 1 represents a conventional design of surgical drape;

Figure 2 represents a variation in the design of the handling bars at one end of the drape shown in Figure 1;

Figure 3 is a view similar to Figure 1 of a surgical drape in accordance with the invention;

Figure 4 is a plan view of the surgical drape shown in Figure 3;

Figure 5 is a plan view from beneath of a suction head in accordance with the invention; and

Figure 6 is a side elevation of the suction head shown in Figure 5;

Figure 7 is a view similar to Figure 6 but shows the suction head secured to a skin surface with the drape and with a foam pad located between the head and the skin surface.

Figure 8 is a perspective view of the drape with a central strip portion of the protective sheet in the course of being removed, and

Figures 9(a)–9(c) illustrate the steps of affixing the dressing assembly to a wound area on a patient's leg and attachment to a negative pressure assembly.

Referring to Figures 1 and 2 of the accompanying drawings, a conventional laminate for use as a surgical drape comprises a thin, flexible, transparent plastics film 1 which is adhesive-coated on one face 2, normally with a high-tack pressure-sensitive adhesive, and is protected with a releasable layer 3. The thin plastics film is conveniently of polyurethane because it transmits moisture. Layer 3 is normally considerably thicker than film 1 and is coated on the surface adjacent to the adhesive with a releasable material such as a silicone to facilitate stripping away from the adhesive-coated film.

In order to facilitate removal of the adhesive-coated film prior to use of the device, handling bars 4 are bonded at each end to the adhesive-coated film 1. Thus, by holding one of the bars 4, the protective layer 3 can be stripped off and the adhesive face applied to the skin of the patient. To facilitate handling of the thin, flexible film 1, a strengthening plastics film 5 is frequently applied to the free face of the plastics film 1. This is generally also transparent or translucent. Film 5 is preferably not bonded with adhesive to film 1, but may remain in contact by reason of electrostatic forces or because of close contact between the two conforming surfaces of film 1 and film 5.

Usually, the surgeon or nurse will wish to strip off the protective layer 5 after the film 1 has been correctly placed on the patient's skin, and this can be facilitated by making partial cuts 6 through the films 1 and 5, so that as the handling bar 4 is drawn upwards from the patient's skin, the adhesive film 1 remains adhered to the patient, while the partial cuts 6 causes separation of the flexible film from the strengthening film 5. Strengthening bars 7 may be provided to hold the lateral edges of the strengthening film 5 and film 1 together with their main parts.

An alternative arrangement is shown in Figure 2, in which the strengthening film 5 is provided with a separate overlapping handling bar 14, to facilitate its removal from the flexible film 1.

Further details of the make-up and manufacture of surgical drapes are given in US Patent No. 5,437,622 and European Patent Application No. 0161865 and the prior art referred to therein, the disclosure of which is incorporated herein.

Referring to Figure 3 and 4, the surgical drape of this invention comprises a protective outer film 20, laminated to a thin, flexible film 21. The flexible film 21 includes an adhesive-coated layer which is protected with a release-coated sheet material 24. Lateral edges of the flexible film 21 are provided with handling bars 23. Thus far, the design is essentially the same as that shown in Figures 1 and 2.

The drape of the present invention differs from the drape shown in Figures 1 and 2 in that an aperture 25 is cut through the strengthening layer 20 and through the flexible layer 21. The other difference compared with the prior art drapes is that the protective releasable layer is formed in at least two sections.

In the embodiments shown in Figures 3 and 4, the central portion of the releasable layer comprises a strip 26, having flaps 27 which overlap the remaining outboard portions of the releasable layer. The purpose of this is to enable the central strip 26 to be removed first, without disturbing the remaining portions of the releasable layer. The drape can then be fitted around the wound area and, if desired, a suction device or other treatment device passed through the aperture 25 and secured to the patient's skin with the peripheral areas of exposed adhesive-coated film.

An example of a device for applying suction to the wound area is illustrated in Figures 5, 6 and 7.

Referring to these Figures, the suction head comprises a flange portion 30 having a tapered edge 31, and a profile which may be of any desired shape but is generally rounded at its edges. On the face of the flange 30 intended for contact with the patient's skin or a foam pad are formed a series of projections 32 which are distributed over the surface of the flange apart from the peripheral edge portion 31.

The purpose of these projections is to provide fluid channels 33 facilitating the flow of fluids from any point of the flange to a central point 34, from which it is intended to apply suction. The suction head includes a connector 35, located above the aperture 34, having a tubular end 36 adapted for receiving and connecting a catheter. The tubular end may have an outwardly tapered portion to facilitate feeding a catheter into the connector. The upper surface 37 of the suction head has a substantially smooth surface.

In use, the connector portion 35 is sized so that it extends through the aperture 25 in the surgical drape shown in Figures 3 and 4, with the adhesive surface around the aperture bonded to the smooth surface 37 of the flange 30. The suction head may be packaged in this condition with the surgical drape so that in use, the strip 26 is removed by pulling on the handles 27 thus exposing the adhesive surface in the vicinity of and surrounding the suction head. The suction head can then fixed in the desired position on the patient's wound and then the remaining portion of the protective film removed to fix the drape to the patient. The flange 30 of the suction head may be somewhat oval as shown in Figure 5, and have dimensions as indicated in this Figure, i.e. a longer dimension of about 95mm and a short dimension of about 70mm. Alternatively, the flange may be circular and be smaller in plan view. For example, the diameter of a circular suction head may be from about 30 to 50mm in diameter, e.g. about 40mm. It has been found that the suction head flange should not overlap the area of the wound. Thus, in the case of smaller wounds a smaller suction head is indicated.

Figure 7 shows the suction head attached to a wound area 71 of a patient 70. The suction head is pressed into firm contact with a flexible, open-celled foam 73, which is itself pressed into contact with the wound area 71. The suction head and foam pad are pressed into contact with the wound area by a surgical drape 20 having an adhesive surface 74. The adhesive surface is bonded to the patient's skin outside the periphery of the foam pad and suction head. It is also bonded to upper surface 37 of the suction head. An aperture is formed in the drape to permit the connector

portion 35 to extend upwardly through the drape. In order to avert the danger of incorrect catheter tubes being fitted to the connector 35, the latter may have a customised cross-section or internal projection such as a rib or key which co-operates with a corresponding slot or key way in the catheter. Alternatively, the catheter may be moulded with a projection or longitudinal rib which co-operates with a corresponding slot or key way in the aperture of the connector 35.

The foam pad may be packaged in a plastic pouch, sterilised by gamma irradiation and supplied in the same box or in other packing units as the suction head and drape.

Figures 8 and 9(a)–(b) illustrate the way in which the drape/suction head combination is fitted to a wound on a patient's skin. In Figure 8, a backing sheet 101 having a release coated surface is removed in the first step from the adhesive face 102 of the drape to expose the face of the connector 30. A pad 103 of foam is positioned over the wound area and the drape placed over the foam paid, the drape being adhered to the skin above and below the pad (Figure 9a). The lateral protective strips 104 and 105 are removed in turn from the drape and the assembly adhered to the skin (Figures 9(b) and 9(c). Finally, the spout 36 is connected to a tube 106 which is then connected to a source of suction, e.g. a pump as described in our above PCT application, in order to apply negative pressure to the wound. The suction head and drape assembly is shown in Figure 8, with the smooth surface 37 adhered to the drape, is conveniently packaged in an easily openable plastic bag or pouch, and sterilised for immediate use.

CLAIMS:-

1. A surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

2. A drape as claimed in claim 1 wherein the strengthening film comprises a polyolefin.

The Patent Office

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**Application No:** GB 9909575.4 **Examiner:** Mrs Susan Chalmers
**Claims searched:** 1-2 **Date of search:** 4 June 1999

## Patents Act 1977
## Search Report under Section 17

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.Q): A5R: RED

Int Cl (Ed.6): A61B: 19/08

Other:

**Documents considered to be relevant:**

| Category | Identity of document and relevant passage | | Relevant to claims |
|---|---|---|---|
| A | GB 0692578 | (MINNESOTA MINING) see especially page 1 lines 18-41, page 4 lines 38-59 and Figure 4 | 1 |
| A | US5437622 | (LABORATOIRE HYDREX) see especially column 2 lines 20-37 and Figure 1 | 1,2 |

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